



Brussels, 10.8.2022  
C(2022) 5915 final

**COMMISSION IMPLEMENTING DECISION**

**of 10.8.2022**

**relating to the designation of "Allogeneic adult liver-derived stem cells" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council**

(Text with EEA relevance)

(ONLY THE ITALIAN TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products<sup>1</sup>, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Unicyte S.R.L. on 20 May 2022 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 14 July 2022 by the Committee for Orphan Medicinal Products and received by the Commission on 22 July 2022,

Whereas:

- (1) The application submitted by Unicyte S.R.L. concerning the medicinal product “Allogeneic adult liver-derived stem cells” was validated on 14 June 2022 under Article 5(4) of Regulation (EC) No 141/2000.
- (2) "Allogeneic adult liver-derived stem cells" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.
- (3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

## *Article 1*

The medicinal product “Allogeneic adult liver-derived stem cells” is designated as an orphan medicinal product for the indication: Treatment of urea cycle disorders. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/22/2685.

## *Article 2*

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

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<sup>1</sup> OJ L 18, 22.1.2000, p.1.

*Article 3*

This Decision is addressed to Unicyte S.R.L., Via Ernesto Lugaro 15, 10126 Turin (TO), Italia.

Done at Brussels, 10.8.2022

*For the Commission*

*Sandra GALLINA*

*Director-General*